

UNOFFICIAL DRAFT RESPONSE --- FOR INTERVIEW ONLY --- DO NOT ENTER
09/919,298

Remarks

Rejections under 35 USC § 112, first paragraph

Claims 1, 3-5 and 8 stand rejected and claims 21 and 22 are rejected for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. To summarize, Examiner contends that "even in light of narrowing of claim language by reciting specific method steps the claims are still broadly drawn to reprogramming any human somatic cell into a pluripotent cell by administering to said cell an agent which promotes cellular reprogramming," (page 4, last paragraph of Examiner's detailed action). The stated basis of this rejection is that although "the agents affect gene expression, ... there is no indication that the gene expression correlates with a specific cell type or cell status," (page 6, last line of first paragraph of Examiner's detailed action).

Claims 1 and 8 have been amended. Claim 1 has been amended to be drawn to a method of producing a *reprogrammed cell*, which is defined in that claim as a cell that expresses telomerase and is capable of expressing any one of neurofilament, cardiac actin or alpha-antitrypsin gene products. The currently amended claim 1 does not contain new matter as support for the production of a reprogrammed cell can be found a page 13, lines 15-16, which describes changes in patterns of gene expression, page 13, lines 18-19, which describes resultant reprogrammed cells, and page 18, lines 13-15, which overtly states that "[t]he present invention is directed to a method of reprogramming adult somatic cells." Furthermore, since (a) the starting somatic cell did not express telomerase, nor have the capacity to express neurofilament, cardiac actin or alpha-antitrypsin gene products prior to the instant method of reprogramming, and (b) the resultant cell did show changes in gene expression after treating with a first, second and third agent, as exemplified by the expression of telomerase by the resultant cell and the demonstration of the capacity of the resultant cell to express neurofilament, cardiac actin or alpha-antitrypsin gene products, then the resultant cell is a reprogrammed cell. Therefore, in view of the arguments and amendments presented above, Applicants request

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that the written description/enablement rejection of claims 1-9 under 35 USC 112, first paragraph be withdrawn and the claims allowed.

Rejection under 35 U.S.C. § 112, second paragraph

The claims 1, 3-5, 8, 21 and 22 stand rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Examiner bases this rejection on the alleged lack of clarity in establishing a "relationship of telomerase expression to practicing the method and its relation ship to a resulting cell," the resulting cell being a pluripotent stem cell (page 8, lines 2-3 of last paragraph of Examiner's detailed action). Claim 1 has been amended to be drawn to a reprogrammed cell, which is defined in the claim as a cell that expresses telomerase. The expression of telomerase is a direct result of the instant reprogramming process, such that the adult somatic cell does not express telomerase prior to undergoing the instant reprogramming process. In view of the amendment to claim 1, Applicants believe the claims particularly point out and distinctly claim the subject of the instant invention. Applicants therefore request the withdrawal of the rejection of the claims under the second paragraph of 35 USC Section 112.

Rejection under 35 U.S.C. § 102(b)

Applicants gratefully acknowledge Examiner's withdrawal of the reject of claims 1, 3 and 4 under 35 USC § 102(b).

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Conclusion

In view of the amendments and arguments set forth in this response to the Office Action of paper no. 16, Applicants believe that the claims are in condition for allowance. Applicants respectfully request that the rejection of the claims be withdrawn and the claims be allowed to issue. If any outstanding issues remain, Examiner is invited to call undersigned Applicant at the number provided to facilitate the efficient prosecution of this case.

Respectfully submitted,

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